



PATENT

TECH CENTER 1600/2900

JAN 18 2001

RECEIVED

1618

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Fischetti et al.

Serial No. 09/844,435

Group: 1618

Filed: April 30, 2001

Examiner: Raj Bawa

The Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

**PROPRIETARY INFORMATION DISCLOSURE STATEMENT**

Sir:

The attached is a proprietary list of patents and patent applications filed by the inventors or the owners of the present invention. Most of the patent applications will not issue before the issue date of the above listed serial number. It is therefore requested that those patent applications on the attached list not issued prior to the issuance of the above listed patent be redacted.

Applicant provides the following summaries of the enclosed prior art, along with a Form PTO-1449, all of which are enclosed.

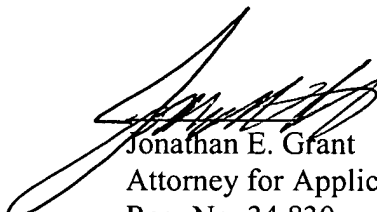
The statement is submitted under the provisions of 37 CFR 1.56 and 1.97(b)(1).

Respectfully submitted,

01/16/2002 MGBREM1 00000097 09844435

01 FC:126

180.00 OP

  
Jonathan E. Grant  
Attorney for Applicant  
Reg. No. 34,830

Jonathan E. Grant  
Grant Patent Services  
2120 L Street, N.W.  
Suite 210  
Washington, D.C. 20037  
(301) 603-9071

no persons are involved in response

RECEIVED  
JAN 18 2007  
TECHNICAL CENTER 1600/2800  
A (1603)  
6551 1631  
COMMERCIAL number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**Complete if Known**

1

of

5

Filing Date

First Named Inventor

Group Art Unit

1618

Examiner Name

BAWA, R.

Attorney Docket Number

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (If known)			
		6,264,945		Fischetti et al.	07-24-2001	
		6,254,866		Fischetti et al.	07-03-2001	
		6,248,324		Fischetti et al.	06-19-2001	
		6,238,661		Fischetti et al.	05-29-2001	
		6,056,955		Fischetti et al.	05-02-2000	
		6,056,954		Fischetti et al.	05-02-2000	
		6,017,528		Fischetti et al.	01-25-2000	
		5,997,862		Fischetti et al.	12-07-1999	
		5,985,271		Fischetti et al.	11-06-1999	
		5,688,501		Merril et al.	11-18-1997	
		4,957,686		Norris	09-18-1990	
		5,604,109		Fischetti et al.	02-18-1997	
		5,882,631		Suga et al.	03-16-1999	
		5,741,487		Asai et al.	04-21-1998	
		6,113,887		Mori et al.	09-05-2000	
		4,122,158		Schmitt	10-24-1978	
		3,983,209		Schmitt	09-28-1976	
		6,113,887		Mori et al.	09-05-2000	
		4,885,163		Shaar et al.	12-05-1989	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
			WO 97 02351 A		CIBA GEIGY AG, et al.	01-23-1997		
			WO 96 07329 A		UNIV. MARYLAND	03-14-1996		
			EP 0 510 907 A		AGRICULTURAL & FOOD RES	10-28-1992		
			WO 99 04809 A		AMBI INC	02-04-1999		

Examiner  
Signature

Date \_\_\_\_\_

Considered

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

**DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

no persons are authorized to respond

PTO/SB/08A (08-01)  
Approved for use through 10/31/2002. OMB 0651-003  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
is a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number		
			Filing Date		
			First Named Inventor		
			Group Art Unit	1619	
			Examiner Name	BAWA	
Sheet	2	of	5	Attorney Docket Number	

[illegible][illegible]

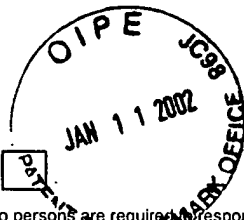
Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08B (08-03)  
Approved for use through 10/31/2002. OMB 0651-0001  
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

3

of

5

### Complete if Known

Application Number

Filing Date

First Named Inventor

Group Art Unit

Examiner Name

Attorney Docket Number

1619

BAWA

### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Reisenger, et al. (1998) "Characterization of Escherichia coli lysis using a family of chimeric E-L Genes" <i>Fems Microbiol Letter.</i> 164(1) p.159-167	
		Sheehan MM, et al. (1997) "The lytic enzyme of the Pneumococcal Phage Dp-1: a chimeric lysis of intergeneric origin." <i>Mol. Microbiol.</i> 25(4) p. 717-725	
		Young et al. (2000) "Phages will out: strategies of host cell lysis." <i>Trends in Microbiology.</i> 8(4) p. 120-127	
		Garcia et al.(1997) "The Pneumococcal cell wall degrading enzymes: A modular design to create new lysins?" <i>Microb. Drug Resist.</i> 3(2): p. 199-211	
		Sheehan MM, et al., (1997) "The Lytic Enzyme of the Pneumococcal Phage Dp-1: a Chimeric Lysin of Intergeneric Origin" <i>Mol. Microbiol.</i> 25(4) p. 717-25	
		Garcia P, et al. (1997) "Bacteriophages of Streptococcus pneumoniae: a molecular approach" <i>Microb. Drug Resist.</i> 3(20) 165-76.	
		Sheehan, MM, et al.(1996) "Analysis of the catalytic domain of the lysin of the lactococcal bacteriophage Tuc2009 by chimeric gene assembling." <i>FEMS Microbiol.Lett.</i> 14(1): p. 23-28.	
		Sanz, JM, et al. (1996) "Construction of a multifunctional pneumococcal murein hydrolase by module assembly." <i>Eur. J. Biochem.</i> 235(3):601-5	
		Lopez R, et al. (1995) "Architecture and Domain Interchange of the Pneumococcal Cell Wall Lytic Enzymes" <i>Dev. Biol. Stand.</i> 85 p. 273-81.	

Examiner  
Signature

Date

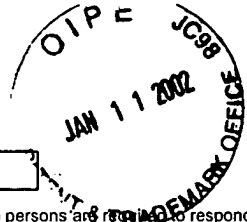
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☐



PTO/SB/08B (08-00)  
Approved for use through 10/31/2002. OMB 0651-0031  
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number		
			Filing Date		
			First Named Inventor		
			Group Art Unit	1619	
			Examiner Name	BAWA	
Sheet	4	of	5	Attorney Docket Number	

RECEIVED  
JAN 18 2001  
TECH CENTER 1600/2900

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Croux, et al.(1993) "Interchange of Functional Domains Switches Enzymes Specificity: Contstruction of a chimeric pneumococcal-clostridial cell wall lytic enzyme." <i>Mol. Microbiology</i> . 9(5) p. 1019-25.	
		Diaz, E. et al. (1990) "Chimeric phage-bacterial enzymes: a clue to the modular evolution of genes. <i>PNAS</i> . 87(20) p. 8125-9.	
		Diaz, E. et al.(1990) "Chimeric pneumoccal cell wall lytic enzymes reveal important physiological and evolutionary traits." <i>J. Biol. Chem.</i> 266(9) p. 5464-71.	
		Lopez, et al. (1997) "The pneumococcal cell wall degrading enzymes: A modular design to create new lysins?" <i>Microbiological Drug Resistance</i> , 3(2) p. 199-211.	
		Loessner, et al. (1999) "Evidence for a holin-like protein gene fully embedded out of frame in the endolysin gene of <i>Staphylococcus aureus</i> Bacteriophage." (1999) <i>Journal of Bacteriology</i> , 181(15) p. 4452-4460.	
		Witte, A et al. (1998) "Characterization of Escherichia coli lysis using a family of chimeric E-L genes." <i>FEMS Microbiol. Lett.</i> , 164(1), p. 159-167	
		Martin, Ana C et al (1998): "Functional analysis of the two-gene lysis system of the pneumococcal phage Cp-1 in homologous and heterologous host cells." <i>Journal of Microbiology</i> 180(2), p. 210-217	
		Oki Masaya et al. (1997) "Functional and structural features of the holin HOL protein of the Lactobacillus plantarum phage phi-gle: Analysis in Escherichia coli system." <i>Gene (AMSTERDAM)</i> 197(1-2) p 137-145.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box → ☐

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08B (2-99)  
Approved for use through 10/31/2002. OMB 0651-0031  
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

5

of

5

Complete if Known

Application Number

Filing Date

First Named Inventor

Group Art Unit

Examiner Name

Attorney Docket Number

1619

BAWA

### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Young, Ry et al. (2000) "Phages will out: strategies of host cell lysis." <i>Trends in Microbiology</i> , 8(3) p 120-127.	
		Nelson, et al. (2001) "Prevention and elimination of upper respiratory colonization of mice by Group A Streptococci by using a bacteriophage lytic enzyme." <i>PNAS</i> . 98 (7) p. 4107-4112	
		Garcia, et al. (1987) "Purification and biochemical characterization of the pneumococcal bacteriophage Cp-1 lysin." <i>Journal of Virology</i> 61(8) p. 2573 - 2580.	
		Loessner, et al. (1996) "Modified Listeria bacteriophage lysin genes (ply) allow efficient overexpression and one-step purification of biochemically active fusion proteins." <i>Applied and Environmental Microbiology</i> . 62(8) p. 3057-3060	

Examiner  
Signature

Date

Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED

JAN 18 2001

TECH CENTER 1600/2900

LIST OF NEW HORIZON PATENTS AND PATENT APPLICATIONS

Patent/Application No.	Country	Filing Date	Issue Date	Inventors	Title
Pat. No. 5,604,109	U.S.A.	09-13-94	02-18-97	Fischetti	A Method for Exposing Group A Streptococci Antigens and an Improved Diagnostic Test for the Identification of Group Streptococcus.
Pat. No. 5,997,862 App No.09/962,523	U.S.A.	10-31-97	12-7-99	Fischetti Loomis	Therapeutic treatment of Group A Streptococcal Infections
Pat. No. 6,017,528 App No. 09/257,025 (Cert. of Correction)	U.S.A.	02-25-99	01-25-00	Fischetti Loomis	Therapeutic Treatment of Group A Streptococcal Infections
Pat. No. 5,985,271 No.09/257,026 (Cert. of Correction)	U.S.A.	02-25-99	11-16-99	Fischetti Loomis	Prophylactic and Therapeutic Treatment of App of Group A Streptococcal Infections
Pat. No. 6,506,954 App.No. 09/395,636 (Cert. of Correction)	U.S.A.	09-14-99	05-02-00	Fischetti Loomis	Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Various Illnesses
Pat. No. 6,238,661 App. No. 09/497,495	U.S.A.	04-18-00	05-29-01	Fischetti Loomis	Use of Bacterial Phage Associated Lysing Enzymes for Treating Various Illnesses
Pat. No. 6,264,945 App. No.09/482,992	U.S.A.	01-14-00	07-24-01	Fischetti Loomis	Parenteral Use of Bacterial Phage Associated Lysing Enzymes for the Therapeutic





Treatment of Bacterial Infections					
Pat. No. 6,056,955 App. No.09/395,637	U.S.A.	09-14-99	05-02-00	Fischetti Loomis	Topical Treatment of Streptococcal Infections
App. No. 09/654,484	U.S.A.	09-01-00		Trudil	The Use of Phage Associated Lytic Enzymes For the Rapid Detection of Bacterial
App. No. 09/654,483	U.S.A.	09-01-00		Fischetti Loomis	A Composition for Treatment of A Bacterial Infection of An Upper Respiratory Tract
Pat. No. 6,254,866 App. No. 09/653,690	U.S.A.	09-01-00	07-03-01	Fischetti Loomis	Use of Phage Associated Lytic Enzymes For Treating Bacterial Infections of the Digestive Tract
App. No. 09/654,482	U.S.A.	09-01-00		Fischetti Loomis	A Composition for Treatment of a Bacterial Infection of the Digestive Tract
Pat. No. 6,277,399 App. No. 09/671,882	U.S.A.	09-28-00	08-21-01	Fischetti Loomis	Compositions Incorporating Bacterial Phage Associated Lysing Enzymes For Treating Dermatological Infections
App. No. 09/671,881	U.S.A.	09-28-00		Fischetti Loomis	A Composition for Treatment of Vaginal Bacterial Infections
App. No. 09/671,880	U.S.A.	09-28-00		Fischetti Loomis	A Composition for Treatment of An Ocular Bacterial Infection
Pat. No. 6,248,324	U.S.A.	09-28-00	06-19-01	Fischetti	Bacterial Phage Associated Lysing

App. No. 09/671,879			Loomis	Enzymes fo Treating Dermatological Infections
App. No. 09/671,878	U.S.A.	09-28-00	Fischetti Loomis	The Use of Bacterial Phage Associated Lytic Enzymes for Treating Dermatological Infections
App. No. 09/671,991	U.S.A.	09-28-00	Fischetti Loomis	A Composition for Treating Dental Caries Caused by Streptococcus Mutans
Pat. No. 6,335,012 App. No. 09/671,992	U.S.A.	09-28-00	01-01-02 Fischetti Loomis	A Method for Treating Dental Caries Caused by Streptococcus Mutans
NOTE: THE USPTO PRINTED THE WRONG TITLE AND THE WRONG CLAIMS				
Pat. No. 6,326,002 App. No. 09/671,990	U.S.A.	09-28-00	12-04-01 Fischetti Loomis	The Use of Bacterial Phage Associated Lysing Enzymes for Treating Bacterial Infections of the Upper Respiratory System
App. No. 09/704,148	U.S.A.	11-02-00	Fischetti Loomis Trudil	The Use of Bacterial Phage Associated Lytic Enzymes to Prevent Food Poisoning
App. No. 09/560,650	U.S.A.	04-28-00	Fischetti Loomis	The Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Various Illnesses
App. No. 09/752,731	U.S.A.	01-03-01	Fischetti Loomis	The Parental Use of Bacterial Phage Associated Lysing Enzymes For The Lysing Enzymes for the Therapeutic

App. No. 09/932,460	U.S.A.	07-13-01	Fischetti Loomis	Treatment of Bacterial Infections  The Use of Bacterial Phage Associated Lysing Enzymes for Treating Various Illnesses
Prov. No. 60/324,089	U.S.A.	09-24-01	Fischetti Loomis	The Use of Bacterial Shuffled and Chimeric Phage Associated Lytic Enzymes for the Prophylactic and Therapeutic Treatment of Colonization and Infections caused By <i>Streptococcus Pneumoniae</i>
App. No. 09/960,472	U.S.A.	09-24-01	Fischetti Loomis	The Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Colonization and Infections Caused by <i>Streptococcus pneumoniae</i>
App. No. 09/908,737	U.S.A.	07-19-01	Fischetti Loomis	Parenteral Use of Bacterial Phage Associated Lysing Enzymes for the Therapeutic Treatment of Bacterial Infections
App. No. 09/910,940	U.S.A.	07-13-01	Fischetti Loomis	The Use of Bacterial Phage Associated Lytic Enzymes to Prevent Food Poisoning
App. No. 09/844,435	U.S.A.	04-30-01	Fischetti Loomis	The Use of Bacterial Phage Associated Lysing Enzymes For

App. No. 09/846,688	U.S.A.	05-02-01	Treating Various Illnesses
PCT/US99/04063	PCT	02-25-99	The Use of Bacterial Phage
N/A	INDIA		Associated Lysing Proteins for the
99909595.3	EPO		Prophylactic and Therapeutic
2000-600679	JAPAN		Treatment of Various Illnesses
2001126302	RUSSIAN FEDERATION		
not yet filed	POLAND		
P19917152-0	BRAZIL		
514260	NEW ZEALAND		
2001-700898	NORTH KOREA		
200105279-4	SINGAPORE		
N/A	CANADA		
145087	ISRAEL		
28767/99	AUSTRALIA		
N/A	CHINA		
			A Means for the Prophylactic and
			Therapeutic Treatment of
			Streptococcal Infections

Fischetti  
Loomis

Fischetti  
Loomis